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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,933	02/10/2004	Michael D. Kluetz	CGL03/0339US01	3155

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EXAMINER	
CHUI, MEI PING	

ART UNIT	PAPER NUMBER
1616	

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04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,933	KLUETZ, M	
	Examiner	Art Unit	
	MEI-PING CHUI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-20,60,62-70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

(1) Receipt of Amendments/Remarks filed on 12/04/2007. Claims 1-4, 6-20 and 70 are presented for examination in this application and claims 5, 21-59, 61, 71 and 74-83 are cancelled.

(2) Receipt of Declaration under 37 C.F.R. Section 1.132 filed on 12/04/2007 is acknowledged and it has been considered by the Examiner.

(3) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL.**

Status of Claims

Accordingly, claims 1-20 and 70 are presented for examination on the merits for patentability.

Withdrawn rejections/objections

1. Applicant's arguments with respect to claims 1-20 and 70-71 have been considered but are moot in view of the new ground(s) of rejection.

Declaration under 37 C.F.R. Section 1.132

The Declaration under 37 C.F.R. Section 1.132 filed on 12/04/2007 is acknowledged and it has been considered by the Examiner.

Applicant argues that the prior art reference, Tiainen et al., does not show a peak amount of particles having a diameter less than 2 microns, as both peaks occur at sizes greater than 2 microns.

The instant invention claims a composition comprising plant sterols, which demonstrate different particle size distribution of one having (first peak) a diameter less than 2 μm and the other (second peak) having a diameter in the range from 2 to about 35 μm. However, Tiainen et al. also showing the microcrystalline plant sterol composition has two different particles size distribution peaks, in which one having diameter between about 2 μm to about 3 μm, and the other one having diameter between about 4 to about 10 μm (Figure 2, Example 3).

Although the prior art and the instant claimed compositions, regarding the plant sterols particle size distribution, are not identical, they are substantially similar. Further, Applicants have not provided evidence to support any unexpected results that is attributable to the particle size.

NEW GROUND(S) OF REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable Tiainen et al. (U.S. Patent No. 6,129,944 on 10/10/2000) in view of Lerchenfeld et al. (U. S. Patent Application No. 2003/0232118 published on 12/18/2003), further in view of Haarasilta et al. (WO 98/58554 published on 12/30/1998).

Applicant Claims

Applicants claim a composition comprising particulate plant sterol(s) having a multi-particle size distribution, wherein said composition is in dispersible aqueous, powder, food or beverage medium.

Determination of the scope and content of the prior art (MPEP 2141.01)

Tiainen et al. teach a product containing a microcrystalline plant sterol, which has a volumetric mean particle size less than 35 μm in diameter (column 2, line 59-64). Tiainen et al. also teach that the preparation of a microcrystalline plant sterol composition results in two different particles size distribution peaks, in which one having diameter between about 2 μm to about 3 μm, and the other one having diameter between about 4 to about 10 μm (Figure 2, Example 3).

Tiainen et al. also teach that the resulting microcrystalline plant sterols do not generate a powdery or sandy taste, and thus do not affect the mouth-feel of the final edible products (column 10, Example 13) and can be utilize in cholesterol-lowering products.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

(1) Tiainen et al. do not explicitly teach that the volume to weighted particle size distribution of said plant sterol(s) has a diameter in the range from 2 to 35 μm. However, the deficiency is cured by the teaching of Lerchenfeld et al.

Lerchenfeld et al. teach a composition comprising a hydrophobic plant sterol (page 2: paragraphs 22, line 7 and page 9, claims 46-49). The plant sterol particulates showed a multi-peak volume-weighted differentiation distribution with the composition (see figure 2, sheet 2 of 2). Lerchenfeld et al. also teach that the plant sterol is an aqueous dispersion, where the particle size is from about 0.1 to about 50 μm in diameter, and more than 50 % of said plant sterol particles within this range possess a diameter from about 0.2 to about 10 μm (Page 2, paragraph 20, line 23-26; page 3, paragraph 26, line 6-8 and page 8-9, claims 37-39).

(2) Tiainen et al. also does not specifically teach the plant sterol composition is a beverage composition, i.e. milk or egg. However, the deficiency is cured by the teaching of Haarasilta et al.

Haarasilta et al. teach a premix composition useful in food industry containing plant sterol and foodstuff ingredients, such as cereal, leguminous plant, milk powder, egg white and other edible or bakery products, etc (page 1:Field of Invention).

Finding of prima facie obviousness Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teachings of Tiainen et al. and Lerchenfeld et al. and further in view of Haarasilta et al. to arrive at the instant invention.

(1) One of ordinary skill would have been motivated to blend or pulverize the plant sterols into very fine particle sizes and distribution, and reasonably expect success and similar results because, as Tiainen et al. suggests, microcrystalline plant sterols do not generate a powdery or sandy taste, and thus do not affect the mouth-feel of the final edible products. Therefore, it would have been obvious for one ordinary skill to pulverize the plant sterols into the desirable and suitable particle size ranges and add it to the edible products.

(2) One ordinary skill would have been motivated to utilize the plant sterol in edible products, i.e. cholesterol-lowering products, and reasonably expect success and similar results because, as Tiainen et al. suggests, the addition of microcrystalline plant sterols do not generate a powdery or sandy taste, and thus do not affect the mouth-feel of the final edible products. Therefore, it would have been obvious to do so by adding plant sterol fine particle into edible foods to promote healthy diets.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the combined teachings of the prior art fairly suggests the instant claims.

Conclusion

No claims are allowed. Applicant's amendment filed and adding new claims necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. C./

Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616